

ocket No.: ATI-0025

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of :
: Youssef L. BENNANI, James T. ANDERSON, Jianmin :
WANG, and Anthony TING : Group Art Unit: 1614
: Serial No.: 10/648,781 :
: Filed: August 27, 2003 : Customer No.: 34610
For: BENZO[1,3]DIOXOLE COMPOUNDS, PHARMACEUTICAL COMPOSITIONS
THEREOF, AND PROCESSES OF MAKING AND USING THE SAME

INFORMATION DISCLOSURE STATEMENT

U.S. Patent and Trademark Office
2011 South Clark Place
Customer Window
Crystal Plaza Two, Lobby, Room 1B03
Arlington, Virginia 22202

Sir:

Pursuant to 37 C.F.R. 1.56, the attention of the Patent and Trademark Office is hereby directed to the reference(s) listed on the attached PTO-1449. One copy of each reference is attached. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the reference(s) be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the indicated date. Applicant reserves the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered. This statement should not be construed as a representation that a search has been made, that information cited in the statement is considered to be and/or is material to patentability, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith. It is further understood that the Examiner will consider information that was cited or submitted to the U.S. Patent and Trademark Office in a prior application relied on under 35 U.S.C. §120. 1138 OG 37, 38 (May 19, 1992).

- X 1. This Information Disclosure Statement is being filed (i) within three months of the U.S. filing date of a U.S. application other than a CPA continued prosecution application under §1.53(d) OR (ii) within three months of the date of entry of the national stage as set forth in §1.491 in an international application OR (iii) **before the mailing date of a first Office Action on the merits**. No certification or fee is required. 37 C.F.R. §1.97(b).
- 2. This Information Disclosure Statement is being filed more than three months after the U.S. filing date AND after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Rejection OR Notice of Allowance OR an action that otherwise closes prosecution in the application. 37 C.F.R. §1.97(c).
- a. I hereby state that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. 1.97(e)(1).

- b. I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. 1.97(e)(2).
- c. Attached is our check no. _____ in the amount of \$180.00 in payment of the fee under 37 C.F.R. 1.17(p). Please credit or debit Deposit Account No. 16-0607 as needed to ensure consideration of the disclosed information. Two duplicate copies of this paper are attached.
- 3. This Information Disclosure Statement is being filed after the mailing date of a Final Rejection OR Notice of Allowance OR an action that otherwise closes prosecution in the application, but on or before payment of the Issue Fee. Attached is our check no. ____ in the amount of \$180.00 in payment of the fee under 37 C.F.R. 1.17(p). Please credit or debit Deposit Account No. 16-0607 as needed to ensure consideration of the disclosed information. Two duplicate copies of this paper are attached. 37 C.F.R. §1.97(d).
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- b. I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. 1.97(e)(2).
- X 4. Others:

During May-July 2003, Applicants conducted computer searches on the STN database. A copy of the results of each computer search is appended hereto. The search results were briefly reviewed. No averment as to the relevance of the search results to the present application is made. Because of the excessive number of documents in the search results, however, copies are not included in this information disclosure statement except for those specifically listed above. Of course, if Examiner requests, a copy of any cited document will be provided, if possible.

Applicants note that the publication date of www.ohsu.edu/hosp-bbb/bbdtherapy.html is not known. Applicants request that for the purpose of performing an action on the merits, the Examiner consider that this document has a publication date prior to the effective filing date of the Applicants' application. If this document is utilized in a rejection, Applicants will try to obtain the date of the document, if necessary.

Regarding the foreign language documents, Applicants note the following:

HU 207 324 is accompanied by a partial translation and is cited and discussed in the present application beginning at page 5.

WO 83/00486 includes an English language abstract and includes chemical structures throughout the document, e.g., Fig. 9.

KEREKES et al., J. Prakt. Chem., 313:923-928 (1971), includes chemical structures throughout the document, e.g., pages 923 and 925.

SCMIDHAMMER et al., Arch. Pharm., 311:664-671 (1978), includes an English language abstract and includes chemical structures throughout the document, e.g., page 668.

MÖHRLE et al., Arch. Pharm., 319:1018-1023 (1986), includes an English language abstract and includes chemical structures throughout the document, e.g., page 1019.

PRIOR et al., Arch. Pharm., 316:737-746 (1983), includes an English language abstract and includes chemical structures throughout the document, e.g., pages 740 and 741.

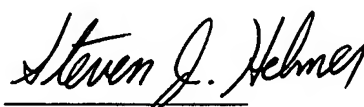
ISRAILOV et al., Chemistry of Natural Compounds, 6:851-852 (1980), includes a chemical structure on page 851.

IIDA et al., Pharmacometrics, 31(4):767-784 (1986), includes an English language abstract and includes chemical structures throughout the document, e.g., page 768.

SEEBACH et al., Helvetica Chimica Acta, 70:1357-1379 (1987), includes an English language abstract and includes chemical structures throughout the document.

X 5. To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 16-0607 and please credit any excess fees to such deposit account.

Respectfully submitted,
FLESHNER & KIM, LLP



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Date: February 3, 2004

DRM\SJH:dep

Please direct all correspondence to Customer Number 34610

**LIST OF PRIOR ART CITED BY
APPLICANT**
(PTO-1449)

ATTY. DOCKET NO.
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GROUP
1614

U.S. PATENT DOCUMENTS

EXAMINER'S INITIALS	*PATENT NO.	*ISSUE DATE	*INVENTOR NAME	CLASS	SUBCLASS	FILING DATE
	3,772,327	11/13/73	BROSSI et al.	260	340.5	07/27/71
	3,946,041	03/23/76	BROSSI et al.	260	340.5	08/08/73
	6,376,516 B1	04/23/02	JOSHI et al.	514	320	09/26/00
	3,905,981	09/16/75	OLOFSON et al.	260	285	10/12/73
	2,946,797	07/26/60	RUDNER	260	286	08/18/58
	4,087,426	05/02/78	SHAMMA et al.	260	286 R	08/16/76

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	2003/0091651 A1	05/15/03	XU	424	539	10/30/01
	2002/0137762 A1	09/26/02	JOSHI et al.	514	291	01/25/02

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	*APPLN. NO.	*FILING DATE	*INVENTOR	CLASS	SUBCLASS	

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EXAMINER'S INITIALS	PATENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	Translation	
						Yes	No
	207 324 B	03/29/93	HUNGARY			Part	
	59044382	12/03/84	JAPAN			Abst	
	62-149677	07/03/87	JAPAN			Abst	
	61-229880	10/14/86	JAPAN			Abst	

OTHER ART (Including Author, Title, Date, Pertinent Pages, Publisher, Place of Publication, Etc.)

	Kerekes and Bogнар, "Synthese des Gnoscopins (DL-Narcotin)," J. Prakt. Chem., 1971, Vol. 313, pp. 923-928.
	Hope and Robinson, "Synthetical Experiments in the Group of the isoQuinoline Alkaloids. Part IV. The Synthesis of β -Gnoscopine," J. Chem. Soc., 1914, Vol. 105, pp. 2085-2104.
	Battersby and Hirst, "Concerning the Biosynthesis of Narcotine," Tetrahedron Letters, 1965, No. 11, pp. 669-673.

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	4,704,458	11/03/87	TAKEDA et al.	546	90	01/23/85
	4,684,732	08/04/87	TANIGUCHI et al.	546	144	03/05/85
	5,013,556	05/07/91	WOODLE et al.	424	450	10/20/89

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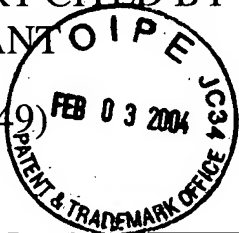
EXAMINER'S INITIALS	PATENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	Translation	
						Yes	No
	61-152686	07/11/86	JAPAN			Abst	
	61-186387	08/20/86	JAPAN			Abst	
	61-233685	10/17/86	JAPAN			Abst	
	62-096491	05/02/87	JAPAN			Abst	
	61-165327	07/26/86	JAPAN			Abst	
	0 152 090	08/21/85	EPO				
	0 161 499	11/21/85	EPO				
	0 201 359	11/12/86	EPO				

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	Schmidhammer and Klötzer, "New Reactions of Phthalidoisoquinoline Alkaloids," Arch. Pharm. (Weinheim), 1978, Vol. 311, pp. 664-671.
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	WO 99/08528	02/25/99	PCT				
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	S. Safe et al., "Metameconine as a Model Compound in the Study of Aromatic Reactions," Canadian Jour. of Chemistry, December 1962, Vol. 40, No. 12, pp. 2402-2408.						
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	J. Marton et al., "Synthesis and Conformational Studies on some Nitro- and Aminophthalideisoquinoline Derivatives," Chemical Monthly, March 1993, Vol. 124, No. 3, pp. 291-297.						
	J. Kardos et al., "Inhibition of [³ H]GABA Binding to Rat Brain Synaptic Membranes by Bicuculline Related Alkaloids," Biochemical Pharmacology, 1984, Vol. 33, No. 22, pp. 3537-3545.						
	Moniot and Shamma, "The Methylene Signature of Reduced Isoquinolines: A PMR Structural Correlation," Heterocycles, 1978, Vol. 9, No. 2, pp. 145-152,						
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	S. Iida et al., "Metabolic Fate of (±)-(R*)-7-Amino-4,5,6-triethoxy-3-[(R*)-5,6,7,8-tetrahydro-4-methoxy-6-methyl-1, 3-dioxolo [4,5-g] isoquinolin-5-yl] phthalide (Tritoqualine) (1) Metabolism of Tritoqualine in Rats, Mice and Dogs," Pharmacometrics, 1986, Vol. 31, No. 4, pp. 767-784.						
	D. Seebach et al., "Diastereoselective Hydroxyalkylations in Position 1 of Tetrahydroisoquinolines and Synthesis of Aporphine, Protoberberine, and Phthalide Alkaloids," Helvetica Chimica Acta, 1987, Vol. 70, pp. 1357-1379.						
	P. Kerekes et al., "Synthesis of Phthalideisoquinoline Alkaloids by Means of Reissert Compounds, I" Acta Chimica, 1978, Vol. 97, No. 3, pp. 353-357.						
	K. Iwasa et al., "Conformations of Phthalideisoquinoline Salts and N-Oxides," Journal of Natural Products, Nov-Dec. 1987, Vol. 50, No. 6, pp. 1083-1088.						
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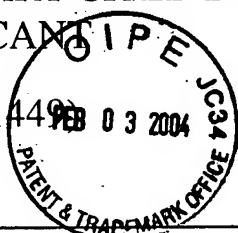
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	Hope and Robinson, "Synthetical Experiments in the Group of the isoQuinoline Alkaloids. Part I. Anhydrocotarninephthalide," J. Chem. Soc., 1911, Vol. 99, pp. 1153-1169.						
	K. Orito et al., "Synthesis of Phthalideisoquinoline and Protoberberine Alkaloids and Indolo[2,1- α] isoquinolines in a Divergent Route Involving Palladium(0)-Catalyzed Carbonylation," J. Org. Chem., 1999, Vol. 64, pp. 6583-6596.						
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	J.P. Wolfe et al., "Simple, Efficient Catalyst System for the Palladium-Catalyzed Amination of Aryl Chlorides, Bromides, and Triflates," J. Org. Chem., 2000, Vol. 65, pp. 1158-1174.						
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	Elango and Shamma, "A Pyrolytic Route to the Phthalide-Isoquinolines," J. Org. Chem., 1983, Vol. 48, pp. 4879-4881.						
	T. Shono et al., "Novel Zinc-Promoted Alkylation of Iminium Salts. New Synthesis of Benzyloisoquinoline, Phthalidylisoquinoline, and Protoberberine Alkaloids and Related Compounds," J. Org. Chem., 1983, Vol. 48, pp. 1621-1628.						
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	Chemical Abstracts, Abstract No. 6638, 1987, p. 1063.
	M.K. Lee et al., "Inhibition of Tyrosine Hydroxylase by Hydrastine," Med. Sci. Res., 1997, Vol. 25, pp. 619-620.
	M. Rahimizadeh et al., "Alkaloids of <i>Fumaria Parviflora</i> Lam, Fumariaceae," Oriental Journal of Chemistry, 1998, Vol. 14, No. 2, pp. 217-220.
	Al-Yahya and Hassan, "Carbon-13 Nuclear Magnetic Resonance of the Isoquinoline Alkaloid, Noscapine and Other Related Compounds," Spectroscopy Letters, 1988, Vol. 21, No. 4, pp. 293-302.
	Internet Article: www.pharmj.com/Editorial/19990904/education/parenteral2.html , Ijeoma F. Uchegbu, "Science in Pharmacy: Parenteral drug delivery: 2," Pharmaceutical Journal, September 4, 1999 Special Feature, Vol. 263, No. 7061, pp. 355-358
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	K. Ye et al., "Opium Alkaloid Noscapine is an Antitumor Agent that Arrests Metaphase and Induces Apoptosis in Dividing Cells," Proc. Natl. Acad. Sci. USA, February 1998, Vol. 95, No. 4, pp. 1601-1606.						
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